

**Ansell**

KD13603

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NOV 13 2001

Micro-Touch® Powder Free Latex Surgical Gloves  
(Protein Label Claim)

- [1] **510(k) Summary**  
Page 1 of 2
- [2]     Submitter:           Ansell Healthcare Products Inc. Inc.  
                              1875 Harsh Avenue SE  
                              Massillon, Ohio 44646
- Contact:           James R. Chatterton
- Telephone:        330-833-2811 x297
- Fax:               330-833-6501
- Date of            October 16, 2001  
          Preparation:
- [3]     Trade Name:        Micro-Touch® Powder Free Latex Surgical Gloves
- Common Name:     Surgical Gloves
- Classification     Surgeon's Glove  
          Name:
- [4]     Legally Marketed   Micro-Touch® Powder Free Latex Surgical Gloves, cleared for the market  
Device to Which           under 510(k) K961632, cleared July 2, 1996.  
Equivalency Is  
Being Claimed:
- [5]     Device               Micro-Touch® Powder Free Latex Surgical Gloves (Protein Label Claim)  
Description:               meet all the current specifications for ASTM D 3577-00, Rubber Surgical  
                              Gloves, Type 1.
- [6]     Intended Use:       Micro-Touch® Powder Free Latex Surgical Gloves (Protein Label Claim) are  
                              sterile disposable devices intended to be worn by operating room personnel  
                              to protect surgical wounds from contamination.

Micro-Touch® Powder Free Latex Surgical Gloves (Protein Label Claim)  
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 Page 2 of 2

- [7] Summary of Technological Characteristics Compared to Predicate Device      Micro-Touch® Powder Free Latex Surgical Gloves (Protein Label Claim) are equivalent to the predicate device in that they have the same following technological characteristics.

Characteristic	Standard
Dimensions	Meets ASTM D 3577-00
Physical Properties	Meets ASTM D 3577-00
Freedom from holes	Meets ASTM D 3577-00
	Meets ASTM D 5151-99
Biocompatibility	Passes Primary Skin Irritation in Rabbits Test
	Passes Guinea Pig Sensitization Test
Micro-Touch® Powder Free Latex Surgical Gloves (Protein Label Claim) have the additional characteristic:	
Protein Label Claim: This latex glove contains 50 micrograms or less of total water extractable protein per gram	Meets ASTM D 5712-99 Standard Test Method for Analysis of Protein in Natural Rubber and Its Products

- [8] Brief Discussion of Non-clinical Tests      Non-clinical test data (see [7] above) indicate that the product meets all applicable ASTM standards, and FDA requirements for biocompatibility and protein label claim.
- [9] Clinical Tests:      Clinical data are not needed for medical gloves or for most devices cleared by the 510(k) process.
- [10] Conclusions Drawn from Non-clinical Tests:      It is concluded that the Micro-Touch® Powder Free Latex Surgical Gloves (Protein Label Claim) are as safe and effective, and perform as well as the predicate product. They meet ASTM listed standards, and FDA requirements for holes and protein labeling claims.
- [11] Other Information Deemed Necessary by FDA      This summary will include any other information reasonably deemed necessary by the FDA.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 13 2001

Mr. James R. Chatterton  
Vice President Regulatory  
Ansell Healthcare Products, Incorporated  
1875 Harsh Avenue, SE  
Massillon, Ohio 44646

Re: K013603

Trade/Device Name: Micro Touch ® Powder Free Latex Surgical Gloves with  
Protein Content Labeling Claim ( 50 Micrograms or Less )  
Regulation Number: 878.4460  
Regulation Name: Surgeon's Glove, Powder-Free  
Regulatory Class: I  
Product Code: KGO  
Dated: October 15, 2001  
Received: October 31, 2001

Dear Mr. Chatterton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

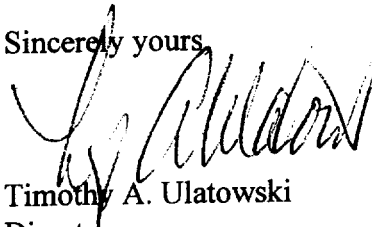
Please be advised that FDA's issuance of a substantial equivalence determination does no

mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

NOV 13 2001

Attachment 2

Indications for Use Statement

K013603

510(k)  
Number  
(if known)

K013603

Device Name

Micro-Touch® Powder Free Surgical Gloves WITH PROTEIN CONTENT LABELING  
CLAIM (50 MICROGRAMS OR LESS)

Indications for Use

Micro-Touch® Powder Free Latex Surgical Gloves are to be worn by operating room  
personnel to protect a surgical wound from contamination.

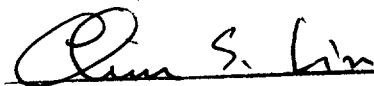
PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF  
NEEDED

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
Per 21 CFR 801.109

OR

Over-The-Counter Use \_\_\_\_\_



(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K013603